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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,049	07/30/2004	Bernd Stahl	STAH3008/REF	2144
23364 7590 06/25/2010 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314-1176				
EXAMINER				
KRISHNAN, GANAPATHY				
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1623				
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06/25/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/502,049

**Applicant(s)**

STAHL ET AL.

**Examiner**

Ganapathy Krishnan

**Art Unit**

1623

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-38, 41-46 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-38, 41-46 and 50-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 4/2/2010 and 4/13/2010 has been received, entered and carefully considered. The following information has been made of record in the instant amendment:

1. Claims 1-31, 39-40, 47-49 and 52 have been canceled.
2. Claims 32-33, 42-46, 50-51 and 53 have been amended. In claims 43, 45-46 and 53 only the claim dependency has been amended.
3. Remarks drawn to claim objection and rejections under 35 USC 112, 2<sup>nd</sup> paragraph, double patenting, 102 and 103.
4. Remarks and Appendix (filed 4/13/2010) further to the Amendment filed 4/2/2010.

The objection to Claim 53 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been overcome by amendment of the claim dependency. Claim 53 now depends from pending claim 32.

The rejection of claims 42 under 35 USC 112, second paragraph has been overcome in view of applicants' explanation and structural representations in the Appendix filed 4/13/2010.

The rejection of Claim 42 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 12-13 of copending Application No. 10/148,193('193) and, the rejection of Claim 42 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent No. 6,576,251 ('251) have been withdrawn. The instant claims are drawn to an oligosaccharide having a particular sequence. The disclosure in the '193 application and the '251 patent are not seen to render obvious the instant claims.

The rejection of claim 47 under 35 USC 102(b) has been rendered moot by cancellation of the claim.

The rejection of Claims 48-49 under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379, of record) in view of Muller et al (Angew. Chem. Intl. Ed. 1993, 32, 477-502, newly cited) has been rendered moot by cancellation of both the claims.

Claims 32-38, 41-46 and 50-53 are pending in the case.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 32-53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is being maintained for reasons of record.

Regarding claim 32 applicants have provided an explanation and also the different possibilities via structures in the Appendix filed 4/13/2010. At # 3 in the Appendix when n=1 and n=2 a rectangular block is shown with the letter 'c' (lower case) inside the block. It also says that V is the connecting point on a carbohydrate residue C (upper case). Since upper case C is defined as HexNAc or Hex or is absent in the claim and upper case C is inside the parentheses in formula I, do applicants intend the lower case 'c' to be a carbohydrate residue other than HexNAc or Hex if present? Clarification is needed. For the purpose of prosecution the carbohydrate residue 'c' shown inside the block in structures 3.1 and 3.2 in the Appendix is seen to be a carbohydrate residue including HexNAc or Hex. Also, in the appendix even though the

carrier is denoted by T and the carbohydrate residue is denoted by 'c', the carrier T is seen to include a carbohydrate residue 'c'. What is intended in claim 32 as explained in the Appendix is not seen to be what is encompassed by the claim recitation because the way formula (II) is attached to formula (I) is not seen to be limited only to the way of attachment as explained in the appendix.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, currently amended claim 33 still recites the broad recitation polymer, biopolymer, and the claim also recites peptide, protein, which is the narrower statement of the range/limitation.

Currently amended Claim 50 recites the terms probe tube food. It is still not clear what this recitation means. A definition is not seen in the specification. For the purpose of prosecution the claim is examined as drawn to food.

Claims 34-38, 41-46, 51 and 53 which depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-35, 37-40 and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Iosa (BE 1006598) is being maintained for reasons of record and is reiterated below.

Iosa teaches the treatment of genital herpes, a viral infection via administration of compositions comprising gangliosides, their salts or esters as active ingredients, especially the gangliosides GM1, GD1a, GD1b and GT1b in combination with a vehicle or excipient (see English Abstract; the patent at page 8, lines 24-33; page 23, lines 4-9). One of the embodiments of the instant method is the administration of the gangliosides GT1b in the said method of treatment (limitations of claims 32, 33(i), 34, 35, 37-genital tract, 38-pharmaceutical, 39, 40-gangliosides). Example 2 (at page 17 of the patent) teaches the treatment of a human patient who is 52 years old (elderly patient as in instant claim 53) with herpes (viral infection; treatment of viral infection in genital tract, limitation of claim 52). This teaching of Iosa is seen to meet the limitations of the said instant claims.

***Response to Applicants Arguments***

Applicants have traversed the rejection of claims 32-35, 37-40 and 52-53 under 35 U.S.C. 102(b) arguing that:

Iosa teaches that his compositions are administered parenterally, whereas in the instant method the compounds are administered orally. Hence Iosa cannot anticipate the instant claims.

Applicants' Arguments have been considered but are not found to be persuasive. At page 9, line 31 through page 10, line 9, Iosa discloses that the compositions containing his compounds can be made in any convenient form including solid or liquid form. Both solid and liquid forms can be administered orally too. Hence Iosa anticipates the instant claims.

The rejection of Claims 42-45 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated Gilbert et al (WO 00/46379, of record) is being maintained for reasons of record and is reiterated below.

Gilbert et al teach a carbohydrate comprising (labeled GT1a-, the saccharide sequence at the bottom in Figure 4), which has all the components as recited in instant formula (I). It also has a neuraminic acid-5-acetate (NeuAc, acyl derivative) attached to the galactose (on the right). This is the same as the Hex attached to X in instant formula (I), wherein Hex is Galactose (Gal) and X is Neuraminic acid –5-acetate. The glucose moiety on the right side of the sequence is the carbohydrate residue or the carrier as instantly claimed. In addition to this Gilbert also teaches gangliosides GD1a, GT1b and GT1c (page 40, Table 1), which are also seen to fit instant formula (I). Gilbert teaches pharmaceutical compositions of his compounds suitable for different modes of administration (limitations of claims 42, 44, 45 and 47. The compositions include other

agents/auxiliaries like buffers tonicity adjusting agents (limitations of claim 43). Gilbert teaches a composition for oral administration comprising the gangliosides of his invention dissolved or suspended in water (page 42, lines 1-6). This constitutes a composition in the form of a beverage as in instant claim 50.

### ***Response to Applicants Arguments***

Applicants have traversed the rejection of claims 42-45 and 50 under 35 USC 102(b) arguing that Gilbert relates to the use of silalyltransferases to make sialated oligosaccharides and monoclonal antibodies. He does not disclose or suggest treating an infection as instantly claimed. A composition for producing antibodies is not a means for treating infections in humans and animals. According to applicants in claims 14-28 C is HexNac or Hex or is absent and not glycosyl as shown in compound GT1a of figure 4. The GT1a compound fails to disclose V.

Applicants' arguments are not found to be persuasive.

The instant claims are drawn to a composition. The fact that Gilbert relates to the use of silalyltransferases to make sialated oligosaccharides and monoclonal antibodies and that he does not disclose or suggest treating an infection as instantly claimed is not relevant. His composition may have been for the purpose of producing antibodies. But is still has the components recited in the instant claims and hence meets the limitations of the instant claims. Intended use of the prior art is not given patentable weight. Formula GT1a of Gilbert has all the structural limitations as explained above. The glucose moiety on the right side of the sequence is the carbohydrate residue or the carrier as instantly claimed, which is V in the instant compound. According to instant claim 32, V can be a carbohydrate residue.



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of Claims 34, 36, 41 and 51-52 under 35 U.S.C. 103(a) as being unpatentable over Iosa (BE 1006598, newly cited) in view of Gilbert et al (WO 00/46379, of record) is being maintained for reasons of record and is reiterated below.

Isoa's and Gilbert's teachings are as above. Isoa teaches that a dosage of 40-100mg of the active agent in one or more dosages (see English abstract and Example 2). However, both Isoa and Gilbert do not specifically teach a method treating an infection via administration of a composition comprising the gangliosides GD1a and GT1c as in instant claim 34, the dosage of 1mg/kg of body weight as recited in claim 36 and the method of treatment of treating an infection in of the gastrointestinal tract in a human as in claims 41 and 52 method of treatment of bacterial infections as in claim 51.

But one of skill in the art reading the teachings of Isoa and Gilbert will recognize that the related gangliosides GD1a and GT1c have the potential for use in methods of treatment as instantly claimed including bacterial infections since their use in the treatment of a variety of conditions is suggested by Gilbert (page 41, lines 20-26).

It would have been obvious to one of skill in the art at the time the invention was made to make the carbohydrates and derivatives of instant formula (I) and their compositions and use them in a method of treatment of infections as instantly claimed since the use of carbohydrates that are structurally close to instant formula (I) and its composition is suggested in the prior art for treating viral infections. Since Gilbert teaches compositions for different modes of administration it includes oral administration too. One of ordinary skill in the art would expect oral administration of the active agents to treat infection in the gastrointestinal tract also.

One of skill in the art would be motivated to use the compounds/compositions as instantly claimed since they are close structural analogs and would look for other such analogs with a high therapeutic index and would also expect them to work with a reasonable expectation of success. Obviousness based on similarity of structure and function entails motivation to make

the claimed compound in expectation that compounds similar in structure will have similar properties. Where prior art compound essentially brackets the claimed compounds and are well known agents for treating infections, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new agents that are close structural analogs. In re Payne, 606 F. 2d 303, 203, USPQ, 245, 254-55 (C.C.P.A. 1979). Applicants also admit in the instant specification (page 10, lines 19-22) the gangliosides that are encompassed by the instant claims are well known compounds. These are also taught by the prior art above.

***Response to Applicants Arguments***

Applicants have traversed the rejection of Claims 34, 36, 41 and 51-52 under 35 U.S.C. 103(a) arguing that:

Isoa teaches a parenteral administration thereby excluding enteral administration. The mode of treating the disease illustrated by Isoa is completely different from the mode of action as taught by the present invention. Gilbert fails to disclose the instant invention as argued above.

Applicants' arguments have been considered but are not found to be persuasive.

At page 10, Isoa discloses that the compositions containing his compounds can be made in solid or liquid form. One of ordinary skill in the art knows that both solid and liquid forms can be administered orally in addition to other modes of administration. Gilbert teaches compound GT1a which is seen to meet the structural limitations of the instant compounds. Instant claim 32 is drawn to a method treating an infection via administration of the compound of formula I. The teachings of Isoa and Gilbert renders obvious the instant claims as explained above. The mode of

action is not relevant. Oral administration of an active agent is easy and convenient in that it can be done by the subject himself/herself.

The rejection of Claims 48-49 under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379, of record) in view of Muller et al (Angew. Chem. Intl. Ed. 1993, 32, 477-502, newly cited) has been rendered moot by cancellation of both the claims.

Hence, the Examiner is not responding to applicants' arguments as it is not relevant.

### ***Conclusion***

Claims 32-38, 41-46 and 50-53 are rejected

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623